

Continuation Application of  
Serial No. 09/007,237  
Preliminary Amendment

**IN THE CLAIMS:**

Please cancel claims 83-110 as being drawn to a non-elected invention in the parent application.

Please consider the following pending claims 1-82, of which claims 1, 2, 10-18, 27-34, 46, 50, 51, 60-66, 78 and 79 have been amended, as attached in clean form as well as in marked-up form showing changes in the amended claims relative to the previous version of the claims according to 37 C.F. R. §1.121(c)(3):

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**Clean Version of Pending Claims 1-82**

30061 → 1 (Amended). An apparatus, comprising:  
an expandable member being sized to be positionable in a sphincter, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter at least 5 mm;  
an energy delivery device coupled to the expandable member, the energy delivery device configured to controllably produce lesions of a sufficient size, number and configuration in an interior of the sphincter so as to create a selectable tightening of the sphincter; and  
a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen.

2 (Amended). The apparatus of claim 1, wherein a configuration of the energy delivery device includes a plurality of energy delivery members distributed on a surface of the expandable member, the apparatus further comprising:

at least one aperture disposed on one of the expandable member or the flexible coupling member, the at least one aperture configured to direct a cooling fluid to cool the energy delivery device.

3. The apparatus of claim 2, wherein the plurality of energy delivery members are radially distributed along a surface of the energy delivery device expandable member.

4. The apparatus of claim 2, wherein the plurality of energy delivery members are longitudinally distributed along a surface of the expandable member.

5. The apparatus of claim 1, wherein the energy delivery device covers a portion of the surface of the expandable member.

6. The apparatus of claim 2, wherein the energy delivery device covers substantially all of an exterior surface of the expandable member.

7. The apparatus of claim 1, wherein the expandable member is sized to be

positionable in a sphincter and to allow the energy delivery device to contact a portion of the inner surface of a sphincter.

8. The apparatus of claim 1, wherein the expandable member is sized to be positionable in a sphincter and to allow the energy delivery device to contact all of an inner surface of the sphincter.

9. The apparatus of claim 1, where the energy delivery device is sized to be positionable in the sphincter and non-permanently dilate the sphincter from a contracted state; and

wherein the sphincter returns to a pretreatment contracted state upon a removal of the expandable member from the sphincter.

10 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to form lesions in a muscle tissue underlying a sphincter mucosal layer.

11 (Amended). The apparatus of claim 1, wherein the deployed state is sized and applies sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm and the energy delivery device is configured to dilate one of a lower esophageal sphincter or an adjoining tissue.

12 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions at a fixed depth from a mucosal surface layer of the sphincter of no more than 4 mms.

13 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and minimizes injury to a mucosal and a submucosal layer of the sphincter.

14 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of sphincter relaxation.

15 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a duration of sphincter relaxation.

16 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of reflux of stomach contents into an esophagus.

17 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of a symptom of reflux of stomach contents into an esophagus.

18 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce an incidence of a sequela of reflux of stomach contents into an esophagus.

19. The apparatus of claim 1, wherein the energy delivery device is positioned on an exterior surface of the expandable member.

20. The apparatus of claim 1, wherein the energy delivery device is positioned on an interior surface of the expandable member.

21. The apparatus of claim 1, further comprising:  
a lumen positioned in an interior of the expandable member.

22. The apparatus of claim 1, wherein the expandable member is expandable.

23. The apparatus of claim 1, wherein the expandable member is a balloon.

24. The apparatus of claim 1, wherein the expandable member is made of an expandable material.

25. The apparatus of claim 1, wherein the expandable member is made of a porous material.

26. The apparatus of claim 1, further comprising:  
an electrolytic solution housed in an expanded expandable member.

27 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy to promote a fibroblast cell infiltration at a site of the lesions.

28 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy to promote a fibroblast growth at a site of the lesions.

29 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy that promotes a myofibroblast cell infiltration at a site of the lesions.

30 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of a lower esophageal sphincter without permanently damaging anatomical structures near the lower esophageal sphincter.

31 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging an aorta positioned near the lower esophageal sphincter.

32 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

33 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

34 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

35. The apparatus of claim 1, wherein the energy delivery device is an RF electrode.

36. The apparatus of claim 35, further comprising:  
an RF energy source coupled to the RF electrode.

37. The apparatus of claim 1, wherein the energy delivery device is a microwave antenna.

38. The apparatus of claim 37, further comprising:  
a microwave energy source coupled to the microwave antenna.

39. The apparatus of claim 1, wherein the energy delivery device is a waveguide.

40. The apparatus of claim 39, further comprising:  
a light source coupled to the waveguide.

41. The apparatus of claim 40, wherein the light source is a laser.

42. The apparatus of claim 1, wherein the energy delivery device is an acoustical transducer.

43. The apparatus of claim 1, wherein the energy delivery device is a resistive heating device.

44. The apparatus of claim 1, further comprising:  
a visualization device coupled to the expandable member.

45. The apparatus of claim 1, further comprising:  
an extension member coupled to the expandable member.

46 (Amended). The apparatus of claim 45, wherein a proximal portion of the extension member is maneuverable by a medical practitioner.

47. The apparatus of claim 1, wherein the energy delivery device is a plurality of RF electrodes.

48. The apparatus of claim 47, wherein the plurality of electrodes is a flexible circuit.

49. The apparatus of claim 1, further comprising:  
a mechanical expansion device coupled to the expandable member.

50 (Amended). An apparatus comprising:  
an expandable member means sized to be positionable in a lower esophageal sphincter and non-permanently dilate the lower esophageal sphincter from a contracted state, the expandable member means having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm;

an energy delivery device means coupled to the expandable member means, the energy delivery device means configured to controllably produce lesions of a sufficient size, number and configuration in an interior of the lower esophageal sphincter to create a tightening of the lower esophageal sphincter;

a flexible coupling member means coupled to the expandable member means, the coupling member means including at least one lumen means and configured to be maneuverable in a body lumen; and,

wherein the lower esophageal sphincter returns to a contracted state upon a removal of the expandable member means from the sphincter.

51 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to controllably produce lesions in an interior of the lower esophageal

sphincter without creating a permanent impairment of the lower esophageal sphincter's ability to achieve a physiologically normal state of closure.

52. The apparatus of claim 50, wherein the energy delivery device is positioned on an exterior surface of the expandable member means.

53. The apparatus of claim 50, wherein the energy delivery device is positioned on an interior surface of the expandable member means.

54. The apparatus of claim 50, further comprising:  
a lumen means positioned in an interior of the expandable member means.

55. The apparatus of claim 50, wherein the expandable member means is expandable.

56. The apparatus of claim 50, wherein the expandable member means is a balloon.

57. The apparatus of claim 50, wherein the expandable member means is made of an expandable material.

58. The apparatus of claim 50, wherein the expandable member means is made of a porous material.

59. The apparatus of claim 57, further comprising:  
an electrolytic solution means housed in an expanded expandable member means.

60 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to deliver energy to the interior of the lower esophageal sphincter and create a fibroblast proliferation in the interior of the lower esophageal sphincter.

61 (Amended). The apparatus of claim 50, wherein the energy delivery device



means is configured to deliver energy to the interior of the lower esophageal sphincter and create a myofibroblast proliferation in the lower esophageal sphincter.

62 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter without permanently disrupting an aorta positioned near the lower esophageal sphincter.

63 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

64 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

65 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

66 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter while creating submucosal lesions in the lower esophageal sphincter.

67. The apparatus of claim 50, wherein the energy delivery device means is an RF electrode means.

68. The apparatus of claim 47, further comprising:  
an RF energy source means coupled to the RF electrode means.

69. The apparatus of claim 50, wherein the energy delivery device means is a microwave antenna means.

70. The apparatus of claim 69, further comprising:  
a microwave energy source means coupled to the microwave antenna means.

71. The apparatus of claim 50, wherein the energy delivery device means is a waveguide means.

72. The apparatus of claim 71, further comprising:  
a light source means coupled to the waveguide means.

73. The apparatus of claim 72, wherein the light source means is a laser means.

74. The apparatus of claim 50, wherein the energy delivery device means is an acoustical transducer means.

75. The apparatus of claim 74, further comprising:  
an acoustical energy source means coupled to the acoustical transducer means.

76. The apparatus of claim 50, wherein the energy delivery device means is a resistive heating device means.

77. The apparatus of claim 50, further comprising:  
a visualization device means coupled to the expandable member means.

78 (Amended). The apparatus of claim 50, further comprising:  
an extension member means coupled to the expandable member means.

79 (Amended). The apparatus of claim 78, wherein a proximal portion of the extension member means is maneuverable by a medical practitioner.

80. The apparatus of claim 50, wherein the energy delivery device means is a plurality of RF electrode means.

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81. The apparatus of claim 80, wherein the plurality of electrode means is a flexible circuit means.

82. The apparatus of claim 50, further comprising:  
a mechanical expansion device means coupled to the expandable member means.

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